Study on the **implementation of Article 17** of Regulation (EU) 2017/745 on medical devices on the EU market **(single-use devices)**

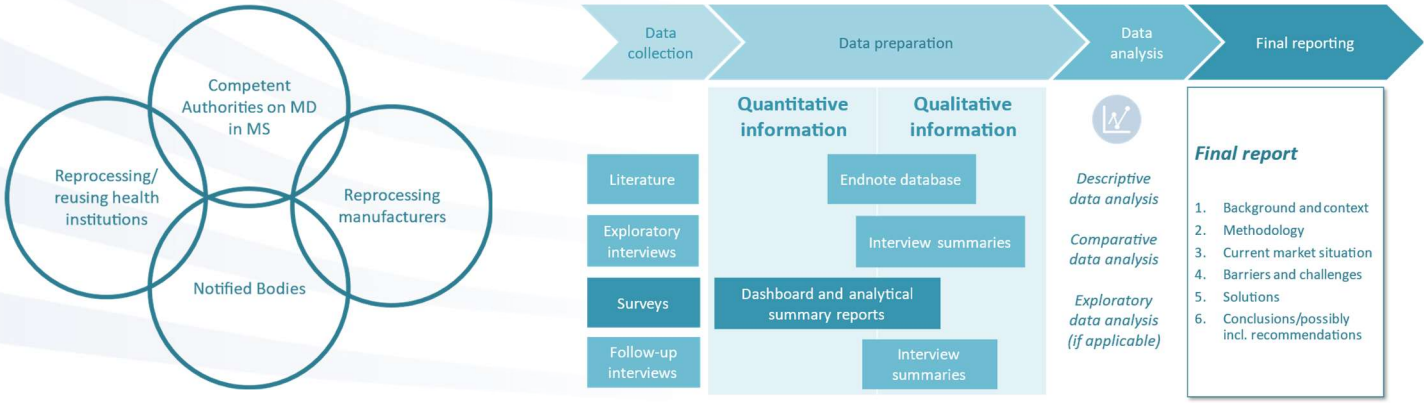
The new Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 (Medical Device Regulation - MDR) is directly applicable EU legislation. However, there are some topics that are reserved for the **Member States to regulate by national law**. This also applies to **Article 17 of the Regulation (EU) 2017/745 on "Single-use devices and their reprocessing"**.

Thus, it lies within the competence of each Member State to decide whether or not to permit the reprocessing of single-use devices, resulting in a large variation in implementation across Europe. The majority of Member States do not allow reprocessing. In order to harmonise procedures for the reprocessing of devices within health institutions, the European Commission has laid down common specifications in the "Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020" laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and the Council as regards common specifications for the reprocessing of single-use devices.

Gesundheit Österreich GmbH (Austrian National Public Health Institute) in collaboration with Agra CEAS Consulting IHS Markit (now part of S&P Global), Areté and Civic Consulting were appointed by the European Commission (via its European Health and Digital Executive Agency / HaDEA) to carry out this study. The **main objective of the study** is to **evaluate how the provisions established in Article 17 of the Regulation (EU) 2017/745 on medical devices (MDR) have been implemented by EU Member States** and how such provisions operate. For this purpose, the current market situation for the reprocessing and reuse of single-use devices in Europe (EU Member States and other countries) will be presented. The study will be carried out over 14 months starting in December 2022.

*The term "**single-use**" is defined in Article 2(8) of Regulation (EU) 2017/745 and relates to a "device that is intended to be used on one individual during a single procedure". It requires that the product is disposed of after use and must not be used a second time. In practice, two harmonised symbols are often used to mark single-use devices.*

*Reprocessing allows a product to be used again: Article 2(39) of Regulation (EU) 2017/745 defines the term "**reprocessing**" as a "process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device". Article 17 of the Regulation (EU) 2017/745 lays down the details of reprocessing.*



The study will utilise a **mixed-methods approach** (literature review, data analysis and stakeholder involvement; see figure above left for the key stakeholders to be addressed) to create a **dashboard presenting indicators and a final report**.

Contact
medical.devices@goeg.at

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